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15.1 Introduction to IMPAACT P1084s

IMPORTANT NOTE: This section of the Manual of Procedures (MOP) provides operational guidance consistent with P1084s protocol Version 2.0. Please refer to prior versions of this section for corresponding guidance applicable to protocol Version 1.0.

IMPAACT P1084s is a substudy of bone, renal and growth outcomes in mothers and infants enrolled in IMPAACT 1077BF and IMPAACT 1077FF, focusing on the effects of exposure to tenofovir disoproxil fumarate (TDF) on these outcomes. Throughout this section, IMPAACT 1077BF and IMPAACT 1077FF are referred to as the main studies and IMPAACT P1084s is referred to as the substudy.

There are two parts of the substudy, the Antepartum Part and the Postpartum Part:

- **The Antepartum Part of P1084s** will involve approximately 475 mother-infant pairs enrolled in the Antepartum Component of the main studies (1077BA and 1077FA). These mother-infant pairs will be enrolled in the substudy during pregnancy and will be followed for substudy outcomes through Week 74 postpartum.

    - ***Under protocol Version 1.0***, enrollment in the Antepartum Part of the substudy was open to all sites but limited to mothers co-infected with Hepatitis B, and their infants, because only these pairs were eligible to receive a TDF-containing prophylaxis regimen in 1077BA and 1077FA.

    - ***Under protocol Version 2.0***, all mother-infant pairs enrolled in 1077BA and 1077FA are potentially eligible for the Antepartum Part of the substudy because all pairs are eligible to receive a TDF-containing prophylaxis regimen in 1077BA and 1077FA. However, to maximize the availability of bone outcome data in the Antepartum Part, enrollment in the Antepartum Part is limited to sites approved to perform dual energy X-ray absorptiometry (DXA) scans.

- **The Postpartum Part of P1084s** involves 400 mother-infant pairs enrolled in the Postpartum Component of 1077BF at DXA sites; enrollment was completed in October 2012 under protocol Version 1.0. Mother-infant pairs enrolled in the Postpartum Part will be followed for substudy outcomes through Week 74 postpartum.

As of the date of this section, the following sites have been approved and are considered "DXA sites" for P1084s: 8052, 8950, 30293, 30300, 30301, 30303, 30306, 30313.

The substudy was designed in complete coordination with the main study. The Schedules of Evaluations (SoEs) for the substudy are harmonized with the SoEs for the main studies, such that substudy data can be combined with main study data and participant burden and specimen collection are minimized. Nonetheless, because the substudy requires additional evaluations beyond those required for the main studies, participants must provide separate written informed consent to take part in the substudy. Participants may decline participation in the substudy and still take part in the main study.

15.2 Participant Accrual for P1084s

A total of approximately 875 mother-infant pairs are expected to be enrolled in P1084s, 475 in the Antepartum Part and 400 in the Postpartum Part. All activated sites are expected to enroll all eligible participants until the accrual target for each part is met across sites. As a condition for study activation, each site has established a study-specific standard operating procedure (SOP) for participant accrual. All sites are responsible for following these SOPs and for updating them if needed to meet their accrual targets.

For each site, accrual into P1084s will begin after all required approvals are obtained and a site-specific study activation notice is issued by the PROMISE Operations Center. Per the DAIDS policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* study sites must document screening and enrollment activity for P1084s on screening and enrollment logs; separate logs should be maintained for the Antepartum and Postpartum Parts.

The Data Management Center (DMC) will report the number of mother-infant pairs enrolled in each part of the substudy to the Protocol Team on a weekly basis. As noted above, accrual into the Postpartum Part was completed in October 2012. Throughout the remainder of the accrual period for the Antepartum Part, the Protocol Team will review accrual and other performance data from each site to determine whether accrual targets should be adjusted across sites to achieve the study objectives most efficiently and to determine when to discontinue accrual at each site. Findings and recommendations from these reviews will be communicated to all sites, and all sites will adjust their accrual efforts accordingly. Similar adjustments may be made after Data and Safety Monitoring Board reviews of the study. The Protocol Team will notify sites when the accrual target is met for the Antepartum Part.

15.3 Informed Consent for P1084s

Please refer to Section 3 of this manual for comprehensive information on informed consent; Section 3.11 details the requirements for obtaining informed consent for P1084s. Briefly, informed consent for mother and infant participation in P1084s must be obtained before enrollment in the substudy. For the Antepartum Part, enrollment in the substudy should ideally occur on the same day as enrollment in the Antepartum Component of the main study (1077BA or 1077FA). However, enrollment is permitted to occur between the enrollment and Week 2 visits of the main study. The informed consent process for the substudy may be conducted at any time before enrollment in the substudy.

As a condition for study activation, each site has established a study-specific SOP for obtaining informed consent. All SOPs must reflect the information provided in Section 3 of this manual. All sites must follow their SOPs for all informed consent processes conducted for this study.

For participants consented and enrolled under protocol Version 1.0, re-consenting is required for continued substudy participation under protocol Version 2.0. See Section 3 of this manual for more information on re-consenting requirements. Source document the re-consenting process in participant study records and record relevant re-consenting details on the Visit Status Report case report form (ADM0040).

15.4 Screening for P1084s: Antepartum Part and Postpartum Part

The term "screening" refers to procedures performed to determine whether potential participants are eligible to take part in the study. The eligibility criteria for the Antepartum and Postpartum Parts of P1084s are specified in protocol Sections 4.1 and 4.2, respectively.

Always refer to the eligibility criteria as specified in current protocol documents, including Letters of Amendment and Clarification Memos.

The information needed to determine eligibility for P1084s is obtained as part of the main study; no additional evaluations are required. However, as indicated above, separate informed consent must be obtained for participation in P1084s.

It is the responsibility of the Investigator of Record (IoR) and other designated study staff to ensure that only participants who meet the eligibility criteria are enrolled in P1084s. Each site must establish a standard operating procedure (SOP) that describes how study staff will fulfill this responsibility; all sites must follow their SOPs when screening all potential participants. Should study staff identify that an ineligible mother-infant pair has been enrolled, the main study Clinical Management Committee (CMC) should be consulted immediately, per the CMC communication procedures in Section 1 of this manual (see Section Appendix 1-2).

15.5 Enrollment (Entry) in the Antepartum Part

For eligible mother-infant pairs, enrollment in the Antepartum Part of P1084s should ideally occur on the same day as enrollment in the main study, prior to initiation of the mother's main study drug regimen. However, enrollment in the Antepartum Part is permitted to occur between the enrollment and Week 2 visits of the main study. Given the allowable window for main study Week 2, enrollment in the Antepartum Part may occur up to 21 days after enrollment in the main study, but must occur prior to the onset of labor.

Eligible mother-infant pairs will be considered enrolled in P1084s upon successful entry of a P1084s eligibility checklist into the Data Management Center's Subject Enrollment System.

A listing of required maternal enrollment (entry) procedures, based on the "Entry" column of protocol Appendix I, is presented on page 5. The first three procedures should be performed first, to confirm eligibility before proceeding to enrollment and performing other P1084s procedures. In addition, given that the required P1084s procedures will be performed on the day of a main study visit, enrollment in P1084s, using the Subject Enrollment System, should occur prior to specimen collection that day, so that specimen collection can be coordinated across the main study and the substudy.

ANTEPARTUM PART OF P1084S
MATERNAL ENTRY
FORM WEEK = WEEK 0

- If not done previously, review main study records and complete eligibility determination/ confirmation for P1084s:
  ⇒ If not eligible, stop
  ⇒ If eligible, continue
- If not done previously, conduct informed consent process for P1084 *(must precede all other procedures listed below):*
  ⇒ If informed consent not obtained, stop
  ⇒ If informed consent obtained, continue
- Complete paper-based eligibility checklist for the Antepartum Part of P1084s, enter checklist data into the Subject Enrollment System to the enroll mother-infant pair, print and file a copy of the confirmation file
- Administer 24 Hour Dietary Recall Questionnaire *(DXA sites only)*
- *If on day of entry into main study,* order phosphorous and calcium testing from sample collected for main study chemistries; *otherwise,* collect blood per the LPC and site SOPs for this testing
- Order phosphorous and calcium testing *(from sample collected for main study chemistries)*
- Collect urine per the LPC and site SOPs for storage
- Document visit per site SOPs and DAIDS policies for source documentation
- Complete and submit all required CRFs
- Enter and export data from the 24 Hour Dietary Recall Questionnaire
- Document enrollment on the P1084s Antepartum Part Screening and Enrollment Log

Although serum chemistry tests required for the main study and the substudy will performed from the same blood sample, the results must be recorded on different case report forms (CRFs). The results of chemistry tests required per the main study SoE must be recorded on main study CRFs and the results of chemistry tests required per the substudy SoE must be recorded on P1084s CRFs.

15.6 Maternal Delivery or Week 1 in the Antepartum Part

For mothers enrolled in the Antepartum Part of P1084s, the SoE specifies evaluations to be performed between the Labor and Delivery (L/D) and Week 1 postpartum visits of the main study. Given the allowable windows for the main study visits, these evaluations may be performed between delivery and Day 14 postpartum. However:

- Cord blood should be collected at L/D *(if reasonably available)*
- Breast milk should be processed and stored for P1084s at the Week 1 postpartum visit *(only for mothers enrolled in 1077BF)*
- DXA scans may be performed up to 21 days postpartum *(only at DXA sites)*

The maternal procedures required at Delivery or Week 1 are presented on page 6. There is no specified ordering or required sequence for these procedures.

ANTEPARTUM PART OF P1084S MATERNAL DELIVERY OR WEEK 1 FORM WEEK = FORM WEEK OF MAIN STUDY L/D VISIT
• Collect cord blood per the LPC and site SOPs *(at L/D, if reasonably obtainable)* • Collect blood per the LPC and site SOPs for serum storage • Order phosphorous and calcium testing *(from sample collected for main study chemistries)* • Order specialized processing and storage of breast milk *(only for breastfeeding mothers in 1077BF, from sample collected for main study at Week 1 postpartum)* • Collect urine per the LPC and site SOPs for storage • DXA scan of spine and hip (*within 21 days postpartum, DXA sites only*) • Document visit per site SOPs and DAIDS policies for source documentation • Complete and submit all required CRFs

In the event of technical or operational problems with the DXA scanner at the time of a maternal Delivery or Week 1 visit, the visit should be conducted per the SoE with the exception that the DXA scans should be skipped. If possible, the scans should be performed at a later date, within 21 days postpartum. Complete a DXA Tracking CRF (DGW0076) at each visit during which DXA scans are expected per the SoE.

15.7 Infant Entry in the Antepartum Part

Mothers and infants are enrolled P1084s as pairs and infants are considered enrolled at the same time point when their mothers are considered enrolled, i.e., upon successful entry of a P1084s eligibility checklist into the Subject Enrollment System. For infants enrolled in the Antepartum Part *(in utero)*, the SoE specifies infant entry procedures to be performed between the infant Birth and Week 1 postpartum visits of the main study. Given the allowable window for the main study visits, these evaluations may be performed between birth and Day 14 postpartum. However:

- Phosphorus, calcium, and creatinine testing should be ordered at the Week 1 postpartum visit *(from the sample collected for main study chemistries)*
- DXA scans may be performed up to 21 days postpartum *(only at DXA sites)*

A listing of required infant entry procedures, based on the "Entry" column of protocol Appendix II, is presented below. Other than the exceptions noted above, there is no specified ordering or required sequence for these procedures.

ANTEPARTUM PART OF P1084S INFANT ENTRY FORM WEEK = 0
• Collect blood per the LPC and site SOPs for serum storage • Order phosphorous, calcium, and creatinine testing *(from sample collected for main study chemistries)* • Collect urine per the LPC and site SOPs for storage • DXA scan of whole body and lumbar spine (*within 21 days postpartum, DXA sites only*) • Document visit per site SOPs and DAIDS policies for source documentation • Complete and submit all required CRFs

In the event of technical or operational problems with the DXA scanner at the time of an infant Entry visit, the visit should be conducted per the SoE with the exception that the DXA scans should be skipped. If possible, the scans should be performed at a later date, within 21 days postpartum. Complete a DXA Tracking CRF (DGW0076) at each visit during which DXA scans are expected per the SoE.

15.8 Enrollment (Entry) in the Postpartum Part

This section is no longer applicable because accrual in the Postpartum Part has been completed. Mother-infant pairs enrolled in the Postpartum Part will continue to be followed as described in Section 15.9 below.

15.9 Maternal and Infant Follow-Up

After completion of the P1084s visits described above, the substudy follow-up visit schedule is the same for all mother-infant pairs, regardless of whether they were enrolled in the Antepartum Part or the Postpartum Part. Mothers will follow the SoE in protocol Appendix I; infants will follow the SoE in protocol Appendix II. As shown in Figures 15-1 and 15-3 below, mothers and infants will complete three scheduled follow-up visits and, while the timing of the first scheduled follow-up visits differs for mothers and infants, the timing of the second and third scheduled follow-up visits is the same for mothers and infants.

The remainder of this section describes maternal and infant follow-up in P1084s. Refer to Section 13 of this manual for comprehensive information on retention of study participants in follow-up.

15.9.1 Maternal Follow-Up Visit Schedule

As shown in Figure 15-1, mothers will complete follow-up visits for P1084s at Weeks 6, 26, and 74 postpartum. All visits should ideally be conducted on the target day but may be conducted on any day within the allowable visit window. The Week 6 visit may be conducted within one week before and one week after the target date (± 1 week window). The Week 26 and Week 74 visits may be conducted within six weeks before and six weeks after the target date (± 6 week window). All target dates are counted from the date of delivery.

Figure 15-1
Maternal P1084s Follow-Up Visit Schedule

Visit	Target Visit Day *	Visit Window	
		Window Opens	Window Closes
Week 6	Day 42	Day 35	Day 49
Week 26	Day 182	Day 140	Day 224
Week 74	Day 518	Day 476	Day 560

* Target visit days are counted from the day of delivery. Day of delivery = day 0.

Every effort should be made to conduct P1084s visits on the same day as a main study visit. For mothers in 1077BA, 1077BP, or 1077FA, main study visits are also scheduled to occur at Weeks 6, 26, and 74 postpartum, with both the main study visit schedule and the substudy visit schedule based on the date of delivery. For mothers in 1077BM or 1077FM, the mother's main study visit schedule will not be based on the date of delivery but, utilizing the allowable visit windows, the P1084s visit should be conducted on the day of the main study visit closest to the target date of the P1084s visit.

The ***form weeks*** assigned to maternal follow-up visits for P1084s differ depending on whether the mother was enrolled in the Antepartum Part or the Postpartum Part, as shown in Figure 15-2 below.

Figure 15-2
Form Weeks for Maternal Follow-Up Visits in P1084s

	Week 6 Postpartum	Week 26 Postpartum	Week 74 Postpartum
Mother Enrolled in Antepartum Part	Form week of main study L/D visit plus 6	Form week of main study L/D visit plus 26	Form week of main study L/D visit plus 74
Mother Enrolled in Postpartum Part	6	26	74

Section Appendix 15-1 contains several examples of assigning form weeks in 1077BF, 1077FF, and P1084s under various scenarios. The form weeks assigned to follow-up visits in P1084s correspond to the form weeks assigned for the main study when the mother is (i) taking part in 1077BA or 1077FA and the Antepartum Part of P1084s or (ii) taking part in 1077BP and the Postpartum Part of P1084s. Otherwise, the form weeks assigned for P1084s differ from the form weeks assigned for the main study.

15.9.2 Infant Follow-Up Visit Schedule

As shown in Figure 15-3 (on page 9), infants will complete follow-up visits for P1084s at Weeks 10, 26, and 74 postpartum. All visits should ideally be conducted on the target day but may be conducted on any day within the allowable visit window. The allowable windows will depend on the infant's main study (1077BF or 1077FF) and, for infants in 1077BF, on whether the infant has achieved complete cessation of breastfeeding, defined as stopping all exposure to breast milk for at least 28 days.

- ***For infants in 1077BF BEFORE complete cessation of breastfeeding is achieved:***
  - The allowable window for the Week 10 and Week 26 visits is ±1 week
  - The allowable window for the Week 74 visit is ±4 weeks

- ***For infants in 1077BF AFTER complete cessation of breastfeeding is achieved:***
  - The allowable window for the Week 10 visit is ±1 week
  - The allowable window for the Week 26 and Week 74 visits is ±4 weeks

- ***For infants in 1077FF:***
  - The allowable window for the Week 10 visit is ±2 weeks
  - The allowable window for the Week 26 and Week 74 visits is ±4 weeks

Main study visits are also scheduled for infants at Weeks 10, 26, and 74 and every effort should be made to conduct P1084s visits on the same day as a main study visit.

The ***form weeks*** assigned to infant follow-up visits for P1084s are the ideal visit weeks, i.e., Weeks 10, 26, and 74. Section Appendix 15-1 contains several examples of assigning form weeks in 1077BF, 1077FF, and P1084s under various scenarios. As shown in the examples, for infants in 1077BA, 1077BP, and 1077FA, the form weeks assigned to follow-up visits in P1084s correspond to the form weeks assigned for the main study.

Figure 15-3, Part A
P1084s Follow-Up Visit Schedule for Infants in 1077BF
Before Complete Cessation of Breastfeeding is Achieved

Visit	Target Visit Day *	Visit Window	
		Window Opens	Window Closes
Week 10	Day 70	Day 63	Day 77
Week 26	Day 182	Day 175	Day 189
Week 74	Day 518	Day 490	Day 546

* Target visit days are counted from the day of birth. Day of birth = day 0.

Figure 15-3, Part B
P1084s Follow-Up Visit Schedule for Infants in 1077BF
After Complete Cessation of Breastfeeding is Achieved

Visit	Target Visit Day *	Visit Window	
		Window Opens	Window Closes
Week 10	Day 70	Day 63	Day 77
Week 26	Day 182	Day 154	Day 210
Week 74	Day 518	Day 490	Day 546

* Target visit days are counted from the day of birth. Day of birth = day 0.

Figure 15-3, Part C
P1084s Follow-Up Visit Schedule for Infants in 1077FF

Visit	Target Visit Day *	Visit Window	
		Window Opens	Window Closes
Week 10	Day 70	Day 56	Day 84
Week 26	Day 182	Day 154	Day 210
Week 74	Day 518	Day 490	Day 546

* Target visit days are counted from the day of birth. Day of birth = day 0.

15.9.3 Maternal and Infant Follow-Up Procedures

The procedures listed below should be performed at all maternal and infant follow-up visits, unless otherwise noted. With the exception that maternal pregnancy testing must precede DXA scanning at Week 74, there is no specified ordering or required sequence for these procedures. DXA scans need not be performed on the same day as other P1084s evaluations but should be performed within the allowable window for each visit.

P1084S MATERNAL FOLLOW-UP WEEKS 6, 26, AND 74 POSTPARTUM	P1084S INFANT VISIT FOLLOW-UP WEEKS 10, 26, AND 74 POSTPARTUM
Administer 24 Hour Dietary Recall Questionnaire *(Weeks 6 and 74; DXA sites only)*	
Administer QLW0171, Global Physical Activity Questionnaire *(Weeks 6 and 74; DXA sites only)*	
Collect blood per the LPC and site SOPs for serum storage	Collect blood per the LPC and site SOPs for serum storage
Order phosphorous and calcium testing *(from sample collected for main study chemistries)*	Order phosphorous, calcium, and creatinine testing *(from sample collected for main study chemistries, if sample collected on same day; if not, collect blood per the LPC and site SOPs for this testing)*
Order specialized processing and storage of breast milk *(only for breastfeeding mothers in 1077BF)*	
Collect urine per the LPC and site SOPs for storage	Collect urine per the LPC and site SOPs for storage
Collect urine per the LPC and site SOPs for pregnancy testing *(ideally on the day of DXA scanning but up to 14 days prior to DXA scanning at Week 74; DXA sites only)*	
DXA scan of spine and hip *(Week 74; DXA sites only)* ***DO NOT perform DXA scans if mother is found to be pregnant.***	DXA scan of lumbar spine *(Week 26; DXA sites only)*
Document visit per site SOPs and DAIDS policies for source documentation	Document visit per site SOPs and DAIDS policies for source documentation
Complete and submit all required CRFs	Complete and submit all required CRFs
Enter and export data from the 24 Hour Dietary Recall Questionnaire (*Weeks 6 and 74; DXA sites only)*	

In the event of technical or operational problems with the DXA scanner, the relevant visit (maternal Week 74, infant Week 26) should be conducted per the SoE with the exception that the DXA scans should be skipped. If possible, the scans should be performed at a later date, within the allowable visit window. Complete a DXA Tracking CRF (DGW0076) at each visit during which DXA scans are expected per the SoE.

15.9.4 Other Considerations for Follow-Up: Early Discontinuation

In the event that a mother or infant withdraws from the substudy before Week 74 postpartum, an Early Discontinuation visit should be conducted, if possible. The procedures listed below should be performed; there is no specified ordering or required sequence for these procedures.

Mothers and infants may withdraw from P1084s and still continue to take part in the main study. In the event of withdrawal from the main study prior to Week 74, however, the participant(s) should be withdrawn from P1084s with a P1084s Early Discontinuation visit conducted if possible.

P1084S MATERNAL EARLY DISCONTINUATION	P1084S INFANT EARLY DISCONTINUATION
Administer 24 Hour Dietary Recall Questionnaire *(DXA sites only)*	
Administer QLW0171, Global Physical Activity Questionnaire *(DXA sites only)*	
Collect blood per the LPC and site SOPs for: • Serum phosphorous and calcium • Serum storage	Collect blood per the LPC and site SOPs for: • Serum phosphorous, calcium, and creatinine • Serum storage
Collect urine per the LPC and site SOPs for storage	Collect urine per the LPC and site SOPs for storage
Document visit per site SOPs and DAIDS policies for source documentation	Document visit per site SOPs and DAIDS policies for source documentation
Complete and submit all required CRFs	Complete and submit all required CRFs
Submit data from the 24 Hour Dietary Recall Questionnaire	

15.9.5 Other Considerations for Follow-Up: Maternal Pregnancy

Mothers who become pregnant during follow-up will not have DXA scans while they are pregnant; however, they will undergo all other study evaluations. Infants of mothers who become pregnant will continue to undergo DXA scans per the SoE.

15.9.6 Other Considerations for Follow-Up: Maternal Death

In the event of maternal death, unless the surviving infant's father had previously provided informed consent for the infant's participation in P1084s, conduct of P1084s study visits and procedures must be stopped until informed consent for continued infant participation is obtained from a legally authorized individual, as defined locally. If informed consent can be obtained from a legally authorized individual, conduct of P1084s study visits and procedures should be resumed, through Week 74 postpartum. If a legally authorized individual cannot be identified, or is identified but does not provide informed consent, the infant must be withdrawn from P1084s. All sites should document their operational plans for managing informed consent following maternal death in study-specific SOPs for obtaining informed consent.

15.9.7 Other Considerations for Follow-Up: Infant Death

In the event of infant death, the surviving mother should ideally remain in follow-up in P1084s through Week 74 postpartum.

15.9.8 Other Considerations for Follow-Up: Abnormalities Identified at Substudy Exit (Week 74)

As indicated above, all mothers and infants should ideally complete final substudy evaluations at Week 74 postpartum. In the event that the Week 74 evaluations cannot be performed within the allowable window, it is preferable for the evaluations to be performed late, rather than missed, in order to collect final substudy data for as many participants as possible. For each Week 74 visit window that may be missed, please email the PROMISE Questions Group with a brief description of the situation and the group will provide operational guidance to you.

For mothers and infants who may have abnormal substudy findings at Week 74, all such findings should ideally be followed to resolution. Consider, for example, infants who may have abnormal calcium values at Week 74:

- For grade 3 and 4 values, follow-up should be consistent with the general guidance for grade 3 and 4 toxicities provided in protocol Appendix II.

- For grade 1 and 2 values, protocol Appendix II does not specify the frequency of follow-up testing. At a minimum, repeat testing should be performed at subsequent scheduled main study visits, until resolution is confirmed. Additional (more frequent) follow-up testing may also be performed at the discretion of the IoR or designee. Consultation on the frequency of follow-up testing is always available from the CMC.

For infants, if an abnormal substudy finding has not resolved by the time of the infant's exit from the main study at Week 104, please contact the PROMISE Questions Group for additional operational guidance at that time. Also contact the PROMISE Questions Group if above-listed guidance cannot be followed for any reason.

All follow-up assessments should be source documented in participant study records. Relevant CRFs should also be completed and entered into eData, so that the resolution is documented in the study database. Per added guidance from the DMC, for participants with findings that will be followed after the P1084s study exit visit:

For the last scheduled visit, i.e., the P1084s Week 74 visit

a. On the Visit Status Report form (ADM0040), question 1 should be completed as "1-Scheduled visit/contact"
b. DO NOT submit an Off Study form (F1601)

For visit(s) when the findings are re-assessed, with further re-assessment expected

a. For the CRFs below, use a calculated week of (last scheduled visit + number of weeks elapsed)
b. Complete and submit an ADM0040:
   i. Question 1 should be completed as "8-Unscheduled visit/contact"
   ii. Record in question 6 the reason why the participant was re-assessed after the study exit visit
c. Complete and submit the necessary clinical or lab form needed to document the findings
d. DO NOT submit an Off Study form (F1601)
e. DO NOT complete other CRFs, such as Event Evaluation or a Study Event Tracking Form

For the visit when the findings are last re-assessed, with no further re-assessment expected

a. For the CRFs below, use a calculated week of (last scheduled visit + number of weeks elapsed)
b. Complete and submit an ADM0040:
   i. Question 1 should be completed as "3-Off study"
   ii. Record in question 6 the reason why the participant was re-assessed after the study exit visit
c. Complete and submit the necessary clinical or lab form needed to document the findings
d. DO submit an Off Study form (F1601)
e. DO NOT complete other CRFs, such as Event Evaluation or a Study Event Tracking Form

15.10 DXA Scan Considerations

15.10.1 Training, Certification, and General Information

Technicians performing maternal and infant DXA scans for P1084s will undergo a training and certification process through the Breast and Bone Density Group (BBDG) at the University of California, San Francisco (UCSF). All technicians will follow the procedures described in the *Operators' Manual for the IMPAACT P1084s Study, Scanning Procedures for Hologic Systems*. This manual serves as the official operational reference for P1084s and serves to standardize scanning procedures across sites.

Prior to substudy initiation at each site, the BBDG will certify that each DXA operator is qualified by performing an expert review of five images of each DXA scan type (adult spine and hip, infant whole body and spine). These scans can be from volunteers or from recent patients with patient identifiers removed. If a DXA operator is unable to perform the infant scans on volunteers or patients prior to study initiation, the site will receive preliminary approval to start the study and the DXA operator will be asked to send scans from the first five infants enrolled for final certification. Each DXA operator must also complete an online training program and provide a copy, if available, of their manufacturer's training certificate and license.

The success of the DXA portion of the study depends on several factors, including the qualifications and dedication of the DXA operators, clear specification and understanding of the study requirements as set forth in the operators' manual, and good lines of communication between the sites participating in the study, the UCSF Quality Assurance Center, and members of the P1084s Protocol Team. Section Appendix 15-2 includes a bone density fact sheet that study staff may use for their own information and for reference when answering participant questions. Section Appendix 15-3 includes further information to share with study mothers about infant DXA scanning procedures.

The DXA scanner will generate a report for each scan performed for each participant. These reports should be filed in participant study records. The scans will be sent to UCSF for centralized reading. The centralized reading of each participant's baseline and final scans will be made available to the site after the last DXA scan is read centrally. However, in the event that a participant experiences a bone fracture during the study, the results of that participant's scans will be provided to the site as soon as the results are available.

DXA scans should not be performed during pregnancy. Pregnancy testing is not required prior to the first maternal DXA scan (which must be completed within 21 days postpartum) but must be performed to exclude pregnancy before the maternal scans required at Week 74 postpartum. At this time point, urine pregnancy testing should ideally be performed on the day of DXA scanning but may be done up to and including 14 days prior to the scan.

15.10.2 Number of Scanning Attempts per Visit

Protocol Appendix III and the *Operators' Manual for the IMPAACT P1084s Study* permit a maximum of three attempts for each scan per visit. Further operational guidance related to this requirement is as follows:

- ***What should we do if an infant is fussy and cannot be settled?*** If an infant is fussy and cannot be settled, he/she should be rescheduled for another visit within the visit window, rather than trying multiple attempts for a scan. However, the maximum number of three attempts per scan per visit applies whether all attempts are made on the same date or on more than one day.

- ***If all allowed attempts were not used at the last visit, may we use those attempts at a subsequent visit?*** No; scan attempts cannot be "banked" and then "borrowed" for another type of scan or for scans at a subsequent visit.

    - For example, if an infant enrolled in the Antepartum Part has a successful whole body scan on the first attempt at entry, the maximum number of attempts for the lumbar spine scan at entry remains three. The two unused scan attempts from the whole body scan cannot be added to the number of attempts allowed for the lumbar spine scan at the same visit.

    - Similarly, if an infant enrolled in the Postpartum Part has a successful lumbar spine scan one the first attempt at entry, the maximum number of scan attempts for the lumbar spine scans at subsequent visits remains three. The two unused attempts from the entry visit cannot be added to the number of attempts allowed at other visits.

As specified in the *Operators' Manual for the IMPAACT P1084s Study*, DXA technicians are asked to submit all attempted scans, including failed attempts, to UCSF. Technicians are also asked to maintain a log or other type of documentation to assist with tracking the number of attempts per scan and per visit for all mothers and infants, to help ensure that the maximum number is not exceeded.

15.10.3 Requesting Central Readings of DXA Scans

Per protocol Section 6.4, central readings of DXA scan results will be made available to study sites for women who experience a fracture during the study. To request central readings from the University of California, San Francisco (UCSF):

- Submit the request for DXA scan reports via e-mail to UCSF as follows: John Shepherd at John.Shepherd@ucsf.edu, Bo Fan at Bo.Fan@ucsf.edu, and Jingyi Yu at jingyi.yu@ucsf.edu; copy PROMISE.questions@fstrf.org on your e-mail message.

- Include P1084s in the subject line of your e-mail message. State your request for DXA scan reports in the body of the message and include your CRS number and the relevant PID. *Do not include any other participant information.*

- UCSF will acknowledge your request via return email, generally within one business day. All persons copied on the original request will be copied on the reply.

- In response to each request, UCSF will post all DXA scan reports for the PID on the "My Research Website." UCSF will notify you via e-mail when the reports have been posted. All persons copied on the original request will be copied on the reply.

Any questions related to interpretation of the scan results should be sent to promise.questions@fstrf.org. Members of the PROMISE Questions Group will consult with the P1084s protocol chair and/or other team members as needed to address these questions.

15.11 Nutrition History Considerations

The maternal nutrition history listed in protocol Appendix I will be performed at DXA sites by administering a 24 Hour Dietary Recall Questionnaire. Administration of this questionnaire will be facilitated through the use of the Dietary and Education and Assessment Kit (DAEK) distributed by the Medical Research Council of South Africa. The DAEK assists interviewers in identifying a participant's food intake during the 24 hours before the interview, determining preparation methods and estimated portion sizes of food consumed. This information will then be utilized to provide a summary of the nutritional content of the food consumed. The DAEK is used in conjunction with the FoodFinder™3 software program. Site staff will enter relevant data into the FoodFinder™3 program and then export the data to the Data Management Center. Detailed instructions for administering the questionnaire and entering and exporting the data are provided in Section Appendix 15-4. The data should be entered as soon as possible after each interview. The data may be exported in real time following each interview or batched and exported within four weeks.

The 24 Hour Dietary Recall Questionnaire is administered only at DXA sites.

15.12 Counseling Considerations

Evaluations performed in P1084s may identify issues requiring counseling of study mothers. For example, administration of the 24 Hour Dietary Recall Questionnaire may identify a need for counseling on maternal nutrition and/or infant feeding. When such needs are identified, study staff should provide and document counseling consistent with the guidelines provided in Section 12 of this manual.

15.13 Laboratory Considerations

All specimen collection, testing, and storage required in P1084s is indicated in the SoEs contained in protocol Appendices I and II. Refer to Section 11 of this manual as well as the Laboratory Processing Charts (LPCs) available on the protocol specific web page for additional information.

15.14 Data Management Considerations

All study visits and procedures conducted for P1084s must be documented in accordance with the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*; refer to Section 2 of this manual for more information on study documentation requirements. The CRFs required to be completed for P1084s are indicated in the data collection forms schedules provided by the DMC. Further study-specific guidance on data management is provided in Section 10 of this manual.

Section Appendix 15-1
Examples of IMPAACT 1077BF, 1077FF, and P1084s Visit Schedules and Form Weeks

Example 1: *This is an example of a mother enrolled in 1077FA* who enters the Antepartum Part of P1084s at her Week 2 visit for 1077FA. This mother completes visits at Weeks 4 and 8 for 1077FA and then delivers her infant two weeks later. The form week assigned to this mother's Labor and Delivery timepoint is therefore Week 10. The form week assigned to the P1084s Delivery or Week 1 timepoint is Week 0. After delivery, this mother is not eligible for 1077FM, so she remains in follow-up in 1077FA and P1084s. The chart below lists the form weeks that will be assigned to the mother and infant study visits through Week 26 postpartum.*

VISIT DATE	MOTHER		INFANT	
	MAIN STUDY	P1084s	MAIN STUDY	P1084s
10-Oct-11	1077FA Entry Form Week = 0			
24-Oct-11	1077FA Week 2 Form Week = 2	P1084s Entry Form Week = 0		
7-Nov-11	1077FA Week 4 Form Week = 4			
5-Dec-11	1077FA Week 8 Form Week = 8			
19-Dec-11	1077FA L/D Form Week = 10	P1084s Deliv or Wk 1 Form Week = 0	1077FA Birth Form Week = 0	P1084s Entry Form Week = 0 or 1
26-Dec-11	Week 1 postpartum 1077FA Week 1 Form Week = 11		Week 1 postpartum 1077FA Week 1 Form Week = 1	
30-Jan-12	1077FA Week 6 Form Week = 16	P1084s Week 6 Form Week = 6	1077FA Week 6 Form Week = 6	
27-Feb-12			1077FA Week 10 Form Week = 10	P1084s Week 10 Form Week = 10
26-Mar-12	1077FA Week 14 Form Week = 24		1077FA Week 14 Form Week = 14	
18-Jun-12	1077FA Week 26 Form Week = 36	P1084s Week 26 Form Week = 26	1077FA Week 26 Form Week = 26	P1084s Week 26 Form Week = 26

**This example would also apply to mothers and infants enrolled in 1077BA and the Antepartum Part of P1084s who do not enter other components of 1077BF and therefore remain in follow-up in 1077BA.*

Example 2: *This is an example of a mother, who is co-infected with Hepatitis B, enrolled in 1077FA* who enters the Antepartum Part of P1084s on the day of enrollment in 1077FA. This mother completes visits at Weeks 2, 4, and 8 for 1077FA and then delivers her infant two weeks later. The form week assigned to this mother's 1077FA Labor and Delivery timepoint is therefore Week 10 and the P1084s Delivery or Week 1 timepoint is Week 0. At Week 1 postpartum, this mother enrolls in 1077FM and continues follow-up in 1077FM and P1084s. The chart below lists the form weeks that will be assigned to the mother and infant study visits through Week 26 postpartum.*

VISIT DATE	MOTHER		INFANT		
	MAIN STUDY	P1084s	MAIN STUDY	P1084s	
10-Oct-11	1077FA Entry Form Week = 0	P1084s Entry Form Week = 0			
24-Oct-11	1077FA Week 2 Form Week = 2				
7-Nov-11	1077FA Week 4 Form Week = 4				
5-Dec-11	1077FA Week 8 Form Week = 8				
19-Dec-11	1077FA L/D Form Week = 10	P1084s Deliv or Wk 1 Form Week = 0	1077FA Birth Form Week = 0	P1084s Entry Form Week = 0 or 1	
26-Dec-11	Week 1 postpartum 1077FM Entry Form Week = 0		Week 1 postpartum 1077FA Week 1 Form Week = 1		
23-Jan-12 (M) 30-Jan-12 (I)	1077FM Week 4 Form Week = 4	P1084s Week 6 Form Week = 6	1077FA Week 6 Form Week = 6		*For these visits, use windows to conduct mother and infant visits on the same day.*
20-Feb-12 (M) 27-Feb-12 (I)	1077FM Week 8 Form Week = 8		1077FA Week 10 Form Week = 10	P1084s Week 10 Form Week = 10	
19-Mar-12 (M) 26-Mar-12 (I)	1077FM Week 12 Form Week = 12		1077FA Week 14 Form Week = 14		
11-Jun-12 (M) 18-Jun-12 (I)	1077FM Week 24 Form Week = 24	P1084s Week 26 Form Week = 26	1077FA Week 26 Form Week = 26	P1084s Week 26 Form Week = 26	

**This example would also apply to mothers and infants enrolled in 1077BA and the Antepartum Part of P1084s in which the mother enters 1077BM while the infant remains in follow-up in 1077BA. Note, however, that the timing of entry into 1077BM may differ from the timing of entry into 1077FM.*

Example 3: *This is an example of a mother enrolled in 1077BA who enters the Antepartum Part of P1084s at her Week 2 visit for 1077BA. This mother completes visits at Weeks 2, 4, and 8 for 1077BA and then delivers her infant two weeks later. The form week assigned to this mother's 1077BA Labor and Delivery timepoint is therefore Week 10 and the form week assigned to the P1084s Delivery or Week 1 timepoint is Week 0. At Week 1 postpartum, the mother and infant enroll in 1077BP and continue follow-up in P1084s. Complete cessation of breastfeeding is achieved in late November 2012 and the mother enters 1077BM in early December 2012. The infant continues 1077BP observational and P1084s follow-up. The chart below lists the form weeks that will be assigned to the mother and infant study visits through Week 74 postpartum.*

VISIT DATE	MOTHER		INFANT	
	MAIN STUDY	P1084s	MAIN STUDY	P1084s
10-Oct-11	1077BA Entry Form Week = 0			
24-Oct-11	1077BA Week 2 Form Week = 2	P1084s Entry Form Week = 0		
7-Nov-11	1077BA Week 4 Form Week = 4			
5-Dec-11	1077BA Week 8 Form Week = 8			
19-Dec-11	1077BA L/D Form Week = 10	P1084s Deliv or Wk 1 Form Week = 0	1077BA Birth Form Week = 0	P1084s Entry Form Week = 0 or 1
26-Dec-11	Week 1 postpartum 1077BP Entry Form Week = 1		Week 1 postpartum 1077BP Entry Form Week = 1	
30-Jan-12	1077BP Week 6 Form Week = 6	P1084s Week 6 Form Week = 6	1077BP Week 6 Form Week = 6	
27-Feb-12			1077BP Week 10 Form Week = 10	P1084s Week 10 Form Week = 10
26-Mar-12	1077BP Week 14 Form Week = 14		1077BP Week 14 Form Week = 14	
23-Apr-12			1077BP Week 18 Form Week = 18	
21-May-12			1077BP Week 22 Form Week = 22	
18-Jun-12	1077BP Week 26 Form Week = 26	P1084s Week 26 Form Week = 26	1077BP Week 26 Form Week = 26	P1084s Week 26 Form Week = 26
16-Jul-12			1077BP Week 30 Form Week = 30	
13-Aug-12			1077BP Week 34 Form Week = 34	
10-Sep-12	1077BP Week 38 Form Week = 38		1077BP Week 38 Form Week = 38	
8-Oct-12			1077BP Week 42 Form Week = 42	
5-Nov-12			1077BP Week 46 Form Week = 46	
3-Dec-12	Week 50 postpartum 1077BM Entry Form Week = 0		Week 50 postpartum 1077BP Week 50 Form Week = 50	
31-Dec-12	1077BM Week 4 Form Week = 4			
28-Jan-13	1077BM Week 8 Form Week = 8			
25-Feb-13	1077BM Week 12 Form Week = 12		1077BP Week 62 Form Week = 62	
20-May-13	1077BM Week 24 Form Week = 24	P1084s Week 74 Form Week = 74	1077BP Week 74 Form Week = 74	P1084s Week 74 Form Week = 74

BONE DENSITY FACT SHEET
for IMPAACT P1084s
Bone and Kidney Health Substudy Staff

What is bone density?

Bone density is a term used to describe the amount of calcium and other minerals in bone tissue, as well as the strength of bones. Bones are living tissues in the body. They undergo break-down and build-up in the body, just like other tissues. To keep bones healthy and strong, the body needs calcium, phosphorus, and vitamin D. Calcium and phosphorus are obtained from the foods we eat. Foods that are particularly good sources of calcium include milk and other dairy products, small fish with bones, and dark green leafy vegetables such as spinach. Foods that are particularly good sources of phosphorous include poultry, fish, and eggs. Vitamin D is needed for the body to absorb calcium. We get vitamin D from food and from exposure to sunlight.

If there is not enough calcium in the body, bones become weak. Bones that are weak have low bone density. People with low bone density are at higher risk of fracture (breaking a bone) due to trauma such as falling. Studies have shown that bone density is generally lower in women, older people, and people who smoke cigarettes, are malnourished, or have HIV/AIDS.

How do we measure bone density?

Bone density is measured by a kind of x-ray called dual energy x-ray absorptiometry (DXA). DXA uses a low power x-ray beam to scan parts of the body. The amount of x-ray radiation a person is exposed to during three DXA scans (as will be done in the study) is about the same as in one chest x-ray and about the same as the amount of natural radiation that a person is exposed to over 10 days. DXA scanning is used throughout the world to study bone density in adults and children.

When a DXA scan is performed, the client lies on a padded table while a scanning arm passes over her. The arm does not touch her, so there is no discomfort involved, and the machine does not make any noises that might be frightening. A DXA scan usually takes less than twenty minutes.

How do we understand DXA scan results?

DXA scan results are analyzed by computer to provide precise measurements of bone density. Each client's results are compared to results from other people of the same sex, age and race. This tells us if the client's results are higher or lower than expected.

What happens to bone density during and after pregnancy and breastfeeding?

During pregnancy and breastfeeding, women share the calcium in their bodies with their babies. A mother's calcium is used to build the baby's teeth and bones and to make breast milk. To provide for the baby's needs, a mother's body naturally increases the amount of calcium absorbed from food. However, some of the calcium needed for the baby is taken from the mother's bones. As a result, after six months of exclusive breastfeeding, a mother's bone density decreases by about 5%. This level of decrease is generally not enough to increase the chance of fracture, and once breastfeeding has stopped and women start to menstruate again, their bone density rises. Women usually quickly gain back all of the bone density lost during pregnancy and breastfeeding. In addition, studies have shown that breastfeeding may actually protect women from losing bone density and having fractures later in life.

Why are we measuring bone density in IMPAACT 1084s?

Previous studies have shown bone density decreases of about 3% in adult men and non-pregnant women taking tenofovir. It is not known whether this same level of decrease may also be seen in pregnant women or breastfeeding women or infants exposed to tenofovir, and what the implications of this might be. IMPAACT 1084s will provide data to answer this important question about use of tenofovir among women and infants.

Section Appendix 15-3
Information for Mothers on Infant DXA Scans

When you come for your baby's first scan, the baby should be dressed in comfortable clothes and please bring a dry diaper. All the clothes will be removed except perhaps for an undershirt, skull cap and diaper. The baby will be swaddled according to the study protocol in order to obtain satisfactory scans of the baby's whole body and spine.

This will be a good time to feed the baby so he or she might to go sleep. The baby will be placed on the scanner table but you will be allowed to stay in the room for the entire time.

Babies enrolled in the Antepartum Part will have two scans taken one of the whole body which will take about 3 minutes and one of the spine which will take less than a minute. (Babies enrolled in the PP Part will have just the spine scan taken). The amount of radiation is minimal. In fact it is less than what the baby receives in 1 day by being alive.

When you come for your baby's second scan, the baby will not need to be swaddled. He or she can be scanned wearing only a dry diaper. Only one scan will be done, of the baby's spine. The baby will be placed on the table and positioned by you (mom) and study personnel. The baby should be fed prior to scanning and wear a dry diaper.

Section Appendix 15-4
Instructions for Administering the P1084s Nutrition History:
24 Hour Dietary Recall Questionnaire

Overview

A nutrition history will be completed for all mothers enrolled in IMPAACT P1084s at DXA sites. The information is collected using a standardized Dietary Assessment and Education Kit (DAEK) at three time points for women in the Antepartum Part of P1084s (Entry, Weeks 6 and 74) and at two time points for women in the Postpartum Part of P1084s (Weeks 6 and 74). Information will be collected via an interviewer administered questionnaire, which will collect specific information on foods and quantities consumed the day (24 hours) before the visit. The DAEK is used in conjunction with the FoodFinder™3 program. The information recorded will be entered on-site into the FoodFinder™3 software program and exported to the Data Management Center (DMC).

Materials

- **Dietary Assessment and Education Kit (DAEK)** – contains the following: Instruction Manual, Food Photo Manual, Food Flash Cards
- **FoodFinder™3 software program** – provided with the DAEK kit to allow the data to be entered and the nutrition information calculated on a local PC.
- **MRC Food Quantities Manual Second Edition (1991) –** provides additional codes for food items that may not be included in the kit.
- **24-Hour Recall Recording Sheet (pages 1-5) –** available on the PROMISE tab in the Forms Management Utility on the DMC Portal
- **Nutrition Assessment Tracking CRF (TRK0089) (page 1 of 1) –** available on the Promise tab in the Forms Management Utility on the DMC Portal and included in CRF notebooks.
- **Data Submission System (DSS)** – located on the PROMISE tab on the DMC Portal, this utility will be used by sites to transmit the data file generated by the FoodFinder™3 software program to the DMC
- **DSS Instructions for P1084S Nutritional Data Submission –** located on the PROMISE tab on the DMC Portal, includes details to assist sites with using the DSS when transmitting the DAEK data file.

Steps to prepare for administering the 24 hour dietary recall questionnaire

1. Ensure that all study staff planned to administer the dietary questionnaires are trained in proper use of the DAEK and associated materials. Training should be based on the procedures for the 24 hour food recall described in the DAEK instruction manual.

2. Ensure that all study staff planned to administer the questionnaires become familiar with the kits, remove food items that are not commonly consumed at the site, and add items/pictures of foods that are commonly consumed.

3. Prepare a separate list of codes of food items that are commonly consumed at the site to allow for easy coding after each questionnaire.

4. Develop site-specific procedures for administering and coding the questionnaires, including quality control and quality assurance procedures, following the procedures described in the DAEK instruction manual.

Steps for administering the 24 hour dietary recall questionnaire

1. Prior to starting a questionnaire, make sure that all required materials are available and easily accessible. These include, the 24 Hour Recall Recording Sheet, photos and models of common food items, and photos or models to display food quantities.

2. In a private, quiet clinic space or interview room, greet the participant and explain the questionnaire procedures to her. Answer any questions and help ensure the participant is comfortable before beginning.

3. Complete the header section of the 24 Hour Recall Recording Sheet: PID, Date of Visit/Patient Contact, Protocol Number (P1084s), Institution Code, Form Week, Seq No, Step No, and Key Operator Code. Below the header section complete the following: Interview Name and Code, Start Date of Meal (the day before the date of patient visit/contact, which is the date being recalled) and tick the corresponding Day of the Week.

4. Administer the questionnaire per the DAEK instruction manual and the "steps for the interviewer" listed on the 24 Hour Recall Recording Sheet. Follow Steps 1 and 2 to complete Sheet 1 on page 3 of the 24 Hour Recall Recording Sheet. Follow Step 3 to complete Sheet 2 on pages 4-5 of the 24 Hour Recall Recording Sheet.

5. When completing Sheet 2, use the DAEK kit materials and MRC Food Quantities Manual to identify food codes and weights. Record the appropriate codes and weights for each food item in the last two columns of Sheet 2. This should ideally be done while the participant is still in the clinic in case information needs to be clarified.

6. After completing the questionnaire, follow site procedures for quality control and quality assurance to ensure that the appropriate food codes and weights have been recorded on all sheets.

Steps for entering the 24 hour recall dietary questionnaire into FoodFinder™3 software program

Enter the data collected on the 24 Hour Recall Recording Sheet as soon as possible after the interview has been completed following the instructions below. A new entry should be generated for each questionnaire; participant data should not be linked. NOTE: Do not submit personal data about the participant. Therefore please be aware of the fields that should be left blank or have substitute values to be entered.

1. Go to Data tab
2. Select individuals
3. Click add to accept
4. Enter individual information as below:

INIDVIUDAL INPUT SCREEN

Code	ENTER *the Patient Number (PID)*
ID#	LEAVE BLANK
First name	ENTER *the Institution Code*
Surname	ENTER *the Form week*
DOB à Age	LEAVE BLANK
Gender	ENTER *the Gender*
Address	LEAVE BLANK
Postal code	LEAVE BLANK
Telephone # (H)	LEAVE BLANK
Telephone # (W)	LEAVE BLANK
Cell Phone #	LEAVE BLANK
Fax #	LEAVE BLANK
E-mail address	LEAVE BLANK

The program will ask you if you want to enter meals for the individual. Then you can proceed to the meal input screen. Refer to the user manual on the individuals tab for more details.

MEALS INPUT SCREEN

1. Enter the information as below:

Meal Date	ENTER *the Start date of meal*
Field Worker	ENTER *the Interviewer name and code*

2. Start entering the meals recorded on the 24 hour recall sheet
3. Complete the filter by section by food item, group, mealtime etc.
4. For quick search select the food item then choose look for field and type in the food item for example, ‘sugar’ then it will list the codes and descriptions, for example:
   4005 brown sugar
   3989 white sugar, granulated
5. Drag a food item into the meal items table as required
6. Input all food items on the completed 24 hour recall sheet and save.

Steps for exporting the data using the FoodFinder™3 software program export utility and transferring the data using the DSS

1. Go to the reports tab

2. Select export analysis

3. Select individuals

4. Choose on the code(PID)

5. CLICK OK

6. Select export everything option and save

7. You then select your destination to save your file which will be an excel document
   Note: The export analysis combines the following four fields: Code *(PID),* First Name *(institution code),* Surname *(form week),* and Meal Date. The food items and nutrition information will also be exported. Refer to the user manual which can be found, when you open the MRC food finder database, below the MRC logo "click here for support"

8. Refer to the DSS Instructions for P1084S Nutritional Data Submission for information on transferring the data to the DMC which can be found on the DMC's Portal (PROMISE tab>Site Support >PROMISE Documentation >General Information). Data file(s) should be transferred to the DMC, at a minimum, within 4 weeks of the interview. Data files can be submitted in real time upon completion of the entry in the FoodFinder™3 software program or the files can be batched and submitted within the 4 week window. Please pay careful attention to the location of files stored on your computer and keep track of which files have already been submitted to the DMC and what is not yet submitted. This is especially important if you will be batch sending files and also to locate files in instances of DMC queries. It may be helpful to create and save the files in a folder on your computer labeled with the month and year in which they are generated. Once you have registered for permission to the DSS following the Instructions for P1084S Nutrition Submission, please submit a test data file to confirm the format of your data. The DMC will send confirmation once the format of your data file has been received and reviewed. Please note the transmission as **TEST** in the comment section when uploading the test data.

Case Report Form Completion

Complete the Nutrition Assessment Tracking case report form (TRK0089) and key this form into eData along with the other case report forms for the visit within 3 weeks of the visit.